PATCH-SIZED FLUID DELIVERY SYSTEMS AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 12/429,451, filed on Apr. 24, 2009, entitled Patch-Sized Fluid Delivery Systems and Methods, now U.S. Publication No. US-2012-0209182-A1, published Aug. 16, 2021, which is a continuation of U.S. patent application Ser. No. 11/704,897, filed on Feb. 9, 2007, entitled Adhesive and Peripheral System and Methods of Medical Devices, now U.S. Pat. No. 8,113,244, issued Feb. 14, 2012, now the entire disclosure of which is incorporated herein by reference.

[0002] U.S. Pat. No. 8,113,244 also claims the benefit of the following U.S. Provisional Applications, all of which are herein incorporated by reference in their entireties:

[0003] U.S. Provisional Application Ser. No. 60/772,313, filed Feb. 9, 2006, entitled Portable Injection System;

[0004] U.S. Provisional Application Ser. No. 60/789,243 filed Apr. 5, 2006, entitled Method of Volume Measurement for Flow Control;

[0005] U.S. Provisional Application Ser. No. 60/793,188 filed Apr. 19, 2006, entitled Portable Injection and Adhesive System; and U.S. Provisional Application Ser. No. 60/889,007 filed Feb. 9, 2007, entitled Two-Stage Transcutaneous Inserter.

[0006] U.S. Pat. No. 8,113,244 is also a Continuation of the following U.S. applications, all of which are herein incorporated by reference in their entireties:

[0007] U.S. application Ser. No. 11/704,899, filed Feb. 9, 2007, entitled Fluid Delivery Systems and Methods now U.S. Pat. No. 8,414,522, issued Apr. 9, 2013;

[0008] U.S. application Ser. No. 11/704,896 filed Feb. 9, 2007, entitled Pumping Fluid Delivery Systems and Methods Using Force Application Assembly, now U.S. Pat. No. 8,585,377, issued Nov. 19, 2013; and

[0009] U.S. application Ser. No. 11/704,897, filed Feb. 9, 2007 entitled Adhesive and Peripheral Systems and Methods for Medical Devices, now U.S. Pat. No. 8,113,244, issued on Feb. 14, 2012.

FIELD OF THE INVENTION

[0010] This application relates generally to patch-sized fluid delivery systems and methods.

BACKGROUND

[0011] Many potentially valuable medicines or compounds, including biologicals, are not orally active due to poor absorption, hepatic metabolism or other pharmacokinetic factors. Additionally, some therapeutic compounds, although they can be orally absorbed, are sometimes required to be administered so often it is difficult for a patient to maintain the desired schedule. In these cases, parenteral delivery is often employed or could be employed.

[0012] Effective parenteral routes of drug delivery, as well as other fluids and compounds, such as subcutaneous injection, intramuscular injection, and intravenous (IV) administration include puncture of the skin with a needle or stylet. Insulin is an example of a therapeutic fluid that is self-injected by millions of diabetic patients. Users of parenterally delivered drugs would benefit from a wearable device that would automatically deliver needed drugs/compounds over a period of time.

[0013] To this end, there have been efforts to design portable devices for the controlled release of therapeutics. Such devices are known to have a reservoir such as a cartridge, syringe, or bag, and to be electronically controlled. These devices suffer from a number of drawbacks including the malfunction rate. Reducing the size, weight and cost of these devices is also an ongoing challenge.

SUMMARY OF THE INVENTION

[0014] In various embodiments of the present invention, a patch-sized housing for a fluid delivery system may include a reusable portion and a disposable portion that is removably engageable with the reusable portion. In terms of fluid delivery management, the disposable portion generally includes all of the fluid management components that come into contact with the fluid (e.g., a fluid path having various valve, pump, and/or dispensing regions bounded by flexible membrane material), while the reusable portion generally includes fluid management components that do not come into contact with the fluid (e.g., various valve actuators, pump actuators, and sensors that interface with the fluid path through the flexible membrane material). The reusable portion generally also includes most, if not all, of the components that would be considered reusable or non-disposable, such as, for example, a controller, an active mechanical assembly including a pump with valve and/or pump actuators and pump motor(s), one or more sensors (e.g., a fluid flow/volume sensor, a temperature sensor), one or more electrical power sources (e.g., a rechargeable battery) and related circuitry (e.g., a battery recharging circuit and a coil for inductively coupling the battery charging circuit to an external power supply), a network interface (e.g., a wireless transceiver with antenna, a wireline interface such as USB), and user interface components (e.g., a pushbutton control). The disposable portion generally includes single-use or limited-use components relating to fluid management, but may also include an integral fluid reservoir and other components, such as a backup power source, a small processor (e.g., to continue certain device operations in the event of a failure, to generate an alarm in the event of a failure, or to provide status information to the reusable portion), and/or an alarm output. The disposable portion may also include, or be configured to support, so-called "sharps" components (e.g., a cannula with cannula delivery needle and an analyte sensor) and an assembly for inserting the sharps into a patient (e.g., a cartridge that holds the sharps and an actuator for inserting the sharps). The substrate and the flexible membrane material of the disposable portion may constitute a fluidic assembly that is configured to fit within a disposable base.

[0015] In certain embodiments, the disposable portion includes a substrate having flexible membrane material thereon and incorporating therein a fluid channel, the fluid channel being part of a fluid path in the disposable portion from a reservoir port to a cannula port and including a series of regions exposed to the flexible membrane material, at least one of such regions being a valve region. The reusable portion includes a control assembly having an active mechanical assembly that interacts mechanically with the regions through the membrane material in such a manner as to achieve pumping of fluid along the fluid path, the active